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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,681	08/13/2001	Laurence S. Sloman	A01P1062	9085

7590 08/15/2003

PACESETTER, INC.
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[REDACTED] EXAMINER

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
3762	3

DATE MAILED: 08/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/929,681	SLOMAN, LAURENCE S.
	Examiner Frances P. Oropeza	Art Unit 3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 8/13/01 (Initial Filing).
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-21 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 8/13/01 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 11-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

In claim 6, “determining a characteristic” lacks antecedent basis.

In claim 11, lines 13-14, “the new value” and “the new pacing pulse energy” lack antecedent basis.

In claim 13, lines 1-2, “the control program” and “the microcontroller” and in line 8, “the memory” lack antecedent basis.

In claim 15, “the elements” and “the array” lack antecedent basis.

In claim 17, “the function” lacks antecedent basis. (It appears claim 17 was intended to depend on claims 16, hence the rejections below are based on this understood intent).

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-9, 11-13 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Callaghan et al. (US 4969460). Callaghan et al. teach automatic output regulation of a pacemaker by changing the operating parameter in response to a change in the pacing pulse energy (figure 11; col. 1 @ 7-15; col. 4 @ 43-45; col. 5 @ 33-36; col. 7 @ 4-13; col. 14 @ 46 – col. 15 @ 10; col. 15 @ 44-65; col. 16 @ 14-17; col. 17 @ 64 – col. 18 @ 4; col. 18 @ 11-16; col. 24 @ 66 – col. 25 @ 5; col. 25 @ 17-22; col. 34 @ 11-15 and 17-19).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 4 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Callaghan et al. (US 4969460) in view of Causey, III (US 5554174). As discussed in paragraph 2 of this action, Callaghan et al. disclose the claimed invention except for the current battery energy level providing a basis for adjusting the operating parameter (claim 4) and creating and using an array to define the new operating value (claim 14), the elements of the array being programmable (claim 15).

As to battery level, Causey, III teaches automatically adjusting stimulation energy using battery level for the purpose including the consideration of time to therapy to ensure an appropriate charge level is delivered to the patient. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the current battery energy level

providing a basis for adjusting the operating parameters in the Callaghan et al. system in order to ensure shock efficacy and avoid the need for additional higher energy stimulations that drain the battery and potentially cause the patient pain (col. 3 @ 13-22; col. 4 @ 7-26; col. 5 @ 19-26).

As to arrays, Causey, III teaches automatically adjusting stimulation energy using arrays, created based on collected data or based on programming, for the purpose of providing a mechanism to define new values for the operating parameters to control the device. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used arrays, created based on collected data or based on programming, in the Callaghan et al. system in order to define an easy method to collect and use known successful operating parameters that ensure shock efficacy, to avoid the need for additional higher energy and higher energy stimulations that drain the battery and potentially cause the patient pain (col. 3 @ 13-22; col. 5 @ 19-26; col. 9 @ 22-30; col. 10 @ 3-22).

5. Claims 10 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Callaghan et al. (US 49694460) in view of Mann et al. (US 5127402). As discussed in paragraph 2 of this action, Callaghan et al. disclose the claimed invention except for the new value of pacing being calculated using a function associated with the operating parameter (claims 10, 16), the function being programmable (claim 17), and the pacing pulse being atrial (claim 19).

As to the function, Mann et al. teach maintaining stimulation pulse amplitude in an implantable device using a feature of limiting the programmed maximum sensor rate based on the detected voltage for the purpose of regulating the current drain. It would have been obvious

to one having ordinary skill in the art at the time of the invention to have used a feature of limiting the programmed maximum sensor rate based on the detected voltage in the Callaghan et al. system in order to extend battery life, avoiding costly, potentially dangerous surgery to replace the battery (col. 1 @ 13-20; col. 3 @ 20-41; col. 6 @ 18-23; col. 6 @ 63 – col. 7 @ 35).

As to the atrial pulse, Mann et al. teach maintaining stimulation pulse amplitude in an implantable device using stimulating pulses to the atria for the purpose of providing more comprehensive stimulation control of the heart in both the atria and the ventricles. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used atrial stimulation in the Callaghan et al. system in order to provide comprehensive cardiac control that enables a high quality of life for the patient (figure 1; col. 4 @ 1-7; col. 5 @ 50-56)

Other Prior Art Cited

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4590941 to Saulson et al. teaches programming pulse width corresponding to charge density.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

Art Unit: 3762

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

JPO
8/7/03

Angela D Sykes

ANGELA D. SYKES
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